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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,136	10/10/2001	Dexu Zhu	524022000100	8877

7590

03/27/2002

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EXAMINER

ZUCKER, PAUL A

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 03/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/975,136

Applicant(s)

ZHU ET AL.

Examiner

Paul A. Zucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☒ Claim(s) 1,2 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in China on 9/26/2001. It is noted, however, that applicant has not filed a certified copy of the Chinese application as required by 35 U.S.C. 119(b).

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

3. Claims 1 and 2 are objected to because of the following informalities: These claims do not end with a period as required. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation "n is an integer between 0-1". There are no integers between 0 and 1. This recitation therefore renders claim 1 indefinite.

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5. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The word "pragnosing" in line 2 does not appear to be an accepted term of art or word in the standard English vocabulary.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Satoh et al (US 4,732,916 03-1988). Satoh discloses (Column 5, line 24- column 6, line 3) the instant claimed carboxylic acid (R = H) of claim 1. Satoh thus anticipates instant claim 1.

Claim Rejections - 35 USC § 103

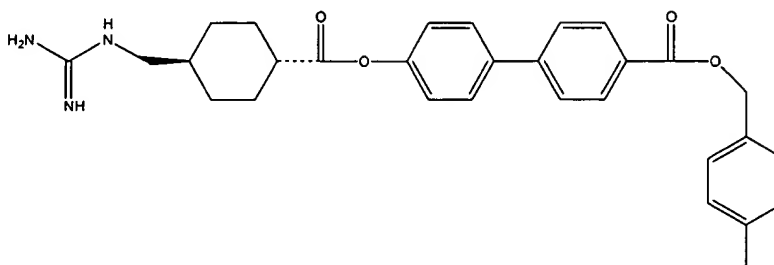
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamoda et al (US 6,284,791 09-2001) and further in view of Oguro et al (US

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4,954,512 09-1990). Kamoda discloses (Column 20, lines 36-61) the following compound as a racemic mixture:



This corresponds to applicant's claimed compound of instant claim 2 with the exception that the cyclohexane ring is replaced by an aromatic benzene ring.

Kamoda further discloses (Column 37, lines 33-64, Table 1, 14th entry) the activity of the compound against *Helicobacter pylori* and *Eschericia coli*. Kamoda teaches (Column 12, line 57- column 13, line 31) methods of treatment and pharmaceutical compositions (with excipients, etc.) of the compounds disclosed for oral administration to humans. Kamoda further teaches (Column 1, line 33 – column 2, line 5) combination therapies using the combination of antibiotics such as amoxicillin and omeplazol, lansoplazol (anti-*H. pylori* agents) which comprises inhibition activity to a proton pump and are used in clinics as anti-ulceration agents and compound containing the guanidine group to treat conditions such as gastritis. The use against resistant strains is implicit in the teaching of combination therapies. The examiner notes that the addition written matter does not impart patentability to a kit

Kamoda is silent with regard to replacing the saturated cyclohexane ring with an aromatic benzene ring. and that the use of an alternative antibacterial against.

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Oguro, however, teaches (Column 2, line 29 –column 3, line 23) genus of closely related anti-ulcer compounds containing the guanidine group. Oguro further teaches the substitution of an aromatic ring for the saturated cyclohexane ring, and *vice-versa* in the position in which applicant has modified the structure disclosed by Kamoda by replacing the saturated cyclohexane ring system with an aromatic benzene ring. Oguro's teaching can therefore be seen as a suggestion to modify the compound disclosed by Kamoda to arrive at the instant compound of claim 3.

Thus it would have been obvious for one of ordinary skill in the art to have performed the instant invention at the time applicant asserts it was made. The motivation would have been produce an anti-ulcer treatment that was easier, and thus cheaper, to make since replacement of the trans-cyclohexyl ring with an aromatic ring removes all stereochemistry from the molecule along with the attendant purification issues. The expectation for success would have been high since both references are directed toward the design of anti-ulcer compounds.

Conclusion


8. Claims 1-20 are outstanding. Claims 1-20 are rejected. Claims 1 and 2 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 703-306-0512. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 703-308-4532. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

PAZ
March 22, 2002


PAUL J. KILLOS
PRIMARY EXAMINER
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